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(71) Applicants *(for all designated States except US):* ROEVIN TRADES LIMITED [GB/GB]; Unit 3, Peerglow Estate, Park Road, Timperley, Cheshire WA14 5QH (GB). REPUBLICAN ENGINEERING AND TECHNICAL CENTRE [SU/SU]; Akademichesky, 8/2, Tomsk, 634055 (SU).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)* : KHACHIN, Vladimir Nikolaievich [SU/SU]; ul. Elizarovykh, 38-20, Tomsk, 634064 (SU). ANOKHIN, Sergei Vladimirovich [SU/SU]; ul. Krasnoarmeiskaya, 101-32, Tomsk, 634034 (SU). PUSHIN, Vladimir Grigorievich [SU/SU]; ul. Pervomaiskaya, 32-22, Sverdlovsk, 630151 (SU). KUZNETSOV, Andrei Vladimirovich [SU/SU]; per. Yutochnyi, 15-2, Tomsk, 634050 (SU). PINKIN, Vladimir Filipovich [SU/SU]; ul. Vavilova, 2-66, Tomsk, 634055 (SU). JURAVLEV, Vladimir Nikolaevich [SU/SU]; Posadskay Street, House 28, Block 4, Flat 66, Sverdlovsk (SU).

(74) Agent: WILLIAMS, POWELL & ASSOCIATES; 34 Tavistock Street, London WC2E 7PB (GB).



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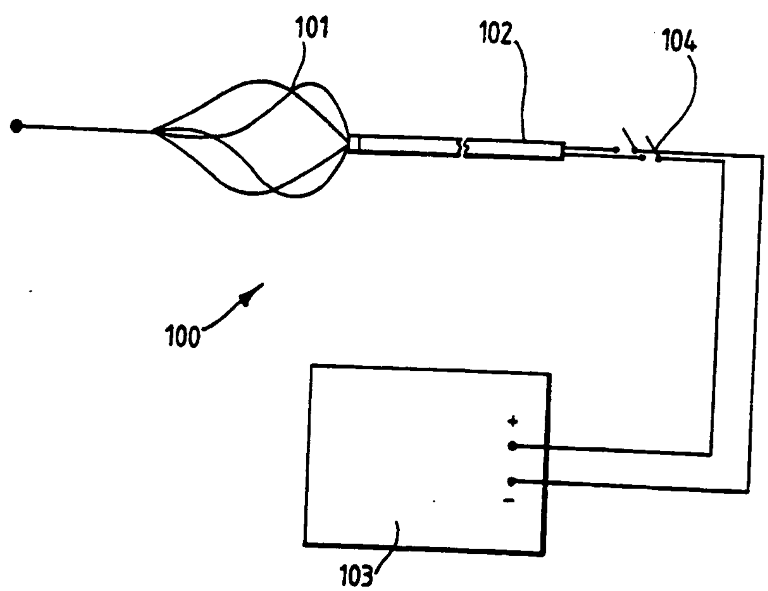



(57) Abstract

A device (100) for extracting a member from a relatively inaccessible location comprises a catheter (102) and wires (101) made of a material having a thermomechanical storage mermory characteristic, e.g. a titanium nickelide composition; the wires are passed into the location with a cross-section similar to that of the catheter and are then heated by a power supply (103) to change their shape to engage the member. The wires may define a basket, a single loop, or two or more loops which can hold between them a member to be extracted, e.g. a calculus or a polyp from a hollow organ. The preferred composition of the wires is: Titanium: 53.5-56.8 %; $TiNi_3$, $Ti_{11}Ni_{14}$, $Ti_2Ni$: 2.0-10.0 %; Nickel: Balance.

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# Extraction Devices

The present invention relates to devices for extracting members from relatively inaccessible locations and more particularly to medical devices which are alternative to surgical procedures and are used for the extirpation of concretions from hollow organs, predominantly calculi from the ureter.

Equipment for extracting calculi from the ureter is widely applied and one known type comprises a catheter, a wire loop-shaped extractor oriented lengthwise to the catheter, and a tool for extending and drawing the loop in the catheter, see for example, 3Fr Ureteroscopic Instruments, Bard Limited, 1989, P.No 8902/6258.

Such equipment has the disadvantages that the calculus may not be caught reliably, that during the traction the calculus can traumatise the ureter walls, and that the equipment has limited capability.

Equipment of another type for extracting calculi from the ureter is known from A.B.Rutner, I.S. Fucilla, An Improved Helical Stone Basket, The Journal of Urology, 116 (1976), p.784-785 and which comprises a catheter, a wire basked-shaped extractor and a facility for controlling the extractor which moves the extractor lengthwise to the catheter. This prior art equipment also has the disadvantages that it has limited capability and that it can traumatise the ureter wall. Extraction by direct traction is difficult and is carried out over a long period of time under the action of a constant load suspended from a mechanism for moving the extractor. These disadvantages are attributable to insufficient dilatation provided by this equipment.

The present invention seeks to enhance the efficiency of the operation with simultaneous decrease of trauma and length of time.

According to a first aspect of the present invention there is provided an extractor device comprising a catheter member characterised in that at one end of the catheter member there is provided one or more wire elements of a material having a thermomechanical shape memory characteristic, and means extending along the catheter member enabling the elements to be heated wherein the shape of the wire elements can be changed, in dependence upon temperature, between a first elongate configuration in which their overall cross-section is substantially the same as or less than that of the catheter member, and a second configuration for extraction.

An advantage of the above device is that it enables members to be extracted from relatively inaccessible locations without damaging the surrounding material.

The means extending along the catheter member may be electrical conductors connected between a controlled power supply and the wire elements. An advantage of this arrangement is its compactness since the shapes of the wire elements are changed by passing electric current through the wire elements themselves. Furthermore, by controlling the length and/or diameter and/or composition of the wire elements, they may be arranged to deform or reconstruct at different rates of power supply and/or at different temperatures. This enables complex operations to be performed.

The wire elements may define at least first and second loops which may be of different sizes. By appropriate

selection of the electric resistance properties of the loops, one may be arranged to deform or reconstruct at a lower temperature than the other, which enables complex operations to be performed. In a modification, this feature may be achieved by providing independently controllable power supplies for the individual loops, but this is not quite as compact.

According to second aspect of the present invention there is provided a method of extracting an article from a relatively inaccessible location employing an extractor device as set out above.

In a preferred arrangement the temperature of the wire elements is controlled between at least three temperatures, a first of which corresponds to the first configuration of the wire elements, and a second of which corresponds to the second configuration of the wire elements. The third temperature may be such as to maintain the material of the wire elements flexible so as not to damage the surrounding material.

Alternatively it may be such as to affect (thermally or otherwise) the member to be extracted, for example it may electrocoagulate a polyp for subsequent examination.

According to third aspect of the present invention, there is provided material displaying a thermomechanical storage memory effect comprising a titanium nickelide composition.

The shape of the extractor device can be selected in dependence upon the situation of the operation performed. Deformation of such an extractor by decreasing its size when the extractor is introduced

into the hollow organ decreases the patient's trauma.

A pulsed power supply with variable pulse duration and pulse repetition rate provides the optimisation of the degree and rate of the extractor shape construction when catching the concretion thus increasing the operative capabilities of the equipment.

Heating the extractor wires by this power supply during the concretion traction makes it possible to control their elastic modulus and, hence, the degree of hollow organ dilatation, thus making the hooking of the walls and the jamming of the concretion less probable. This decreases the trauma and lowers the probability of complications and the time of operation performed.

The connection of the wire extractor with the power supply as a coaxial cable with external and internal Teflon insulation provides the catheter with a minimal cross-section, which lowers the trauma of its introduction, and with lengthwise rigidity and lateral flexibility to smooth turns. Teflon provides a low friction coefficient for the catheter, and thermal protection for the surrounding tissues. All these facts decrease trauma, time of operation, and probability of complication. The use of an extractor in the form of a pear-shaped basket oriented with its widened portion toward the catheter permits the introduction of the concretion through a widened portion of the basket, more reliable holding of the concretion in the narrow portion of the basket and increases the degree of dilatation of the hollow organ during the concretion traction. This lowers trauma and time of operation, since the probability of snagging the concretion in the hollow organ becomes lower.

The thermo- and electro-insulating coating of the extractor wire elements,together with the increase of electric safety and the decrease of thermal action on the surrounding tissues make it possible to achieve increased (with respect to the surrounding tissues) temperature of the extractor which increases the elastic modulus of its elements, decreases the deformation degree of the extractor during the traction and, hence, widens the operative capabilities, decreases trauma and time of operation. Moreover, the insulating coating of the extractor wire elements makes them somewhat thicker thus decreasing the specific hollow organ pressure.

The use of Teflon as a material for coating the extractor wire elements is attributed to its thermoresistance, low coefficient of mechanical friction that leads to additional reduction of traumatism.

Preferred embodiments of the present invention will now be described below with reference to the accompanying drawings, of which:

Figure 1 is a general block diagram of equipment in accordance with the present invention for extracting concretions from hollow organs;
Figure 2 is a block diagram of a pulsed power supply for use with embodiments of the present invention;
Figure 3 shows schematic views of a catheter and an extractor partially in longitudinal section, of a first embodiment of the present invention;
Figure 4 shows schematic views of an extractor in accordance with a second embodiment;
Figure 5 shows schematic views of a two-loop wire extractor in accordance with a third embodiment; and

Figures 6 and 7, 8 are schematic views of single-loop extractors in accordance with further embodiments of the present invention.

Referring to the drawings, equipment 100 for extracting concretions from hollow organs comprises a wire extractor 101 made of a material with thermo-mechanical shape memory effect, a flexible catheter 102, and a controlled power supply 103 connected via its output 104 to the extractor 101.

The material of the extractor 101 preferably comprises titanium and nickel, preferably in the form of titanium, nickel and a titanium nickelide compound. A preferred composition by weight is 53.5 to 56.89 titanium, 7.0 to 10% of a titanium nickelide compound of the form $TiN_3$, $Ti_{11}Ni_{14}$,$Ti_2Ni$, with the balance comprising nickel.

The controlled power supply 103 comprises a pulsed power supply with variable pulse duration and pulse repetition rate. It comprises a processor 105 connected to a control terminal 106, an oscillator 107, a display 108, and a current pulse shaper 109. The output of pulse shaper 109 constitutes the output 104 of the power supply 103.

The connection of the wire extractor 101 to the power supply 103 is made as a coaxial line formed of an internal conductor 10, its insulating coating 11, an external tubular conductor 12, and its insulating coating 13 which can be made of Teflon. The elements 10-13 form the catheter 102 (Fig. 1) of the proposed equipment.

In the embodiment of Fig. 3, the wire extractor 301 is

constructed as a pear-shaped basket oriented with its widened part towards the catheter 302. Each wire 14 of the extractor is made of the material with thermo-mechanical shape memory effect and is provided with an insulating coating 15, e.g. made of Teflon.

Figure 4 shows an extractor 401 made as a basket formed of six (i.e. an even number) wires which are connected electrically (e.g. by soldering) at distal end 16 to each end to a guide wire 22. Half, i.e. three, of the wires are connected at their ends adjacent catheter 402 to the internal conductor 10. The ends of the other half of the wires are connected to the external tubular conductor 12 of the coaxial line forming the catheter 402. Thus half of the wires 14 of the extractor are connected to each power supply terminals 103. This provides equal heating of all of the catching basket wire elements, complete radial symmetry of shape reconstruction and additional increase of the element elastic modulus, i.e. ensures that the dilatation of a hollow organ is uniform in all radial directions.

When they are to be introduced into the body, the extractors 301, 401 shown in Figs. 3a and 4a are deformed by helical torsion in the longitudinal direction to the catheter 302, 402 and their shapes are then as shown in Figs. 3b and 4b, respectively.

Figure 5a depicts an extractor 501 intended for catching a concretion which is almost inaccessible due to its complete overlapping of the gap in the hollow organ. The extractor 501 is made in the form of two wire loops 17 and 18 with different lengths. The longer wire loop 17 is additionally curved as an arc orthogonally to the plane of the principal loop bend, and the shorter one 18 is oriented as a connector for

the end points of the additional arc bend of the loop 17. The divided ends of each of the loops 17 and 18 are connected with the individual conductors 10 and 12 through a coaxial line forming the catheter. Figure 5b shows two-loop extractor 501 in which its elements are deformed into the positions which are occupied by the wire loops 17 and 18 during introduction into the hollow organ. In this configuration, the narrow loop 17 can be moved past the concretion before adopting its Fig. 5a configuration.

The extractor may reconstruct its shape by parts as follows: first, the small (short) loop 18 does, since its resistance is lower and current is higher, then the elongated (large) loop 17 reconstructs its shape since its electrical resistance is higher. Thus there are achieved the efficient catching with limited access and the effective extraction of the concretion due to rotational force at the initial moment of traction.

Figure 6a depicts another extractor 601 intended for extracting or transporting calculi in a hollow organ which are almost inaccessible for catching due to complete overlapping of its gap. It has the form of a single wire loop 19 oriented laterally to the catheter 2. Figure 6b depicts the extractor loop 19 position aligned with the catheter 2 intended for the extractor introduction into the hollow organ.

Another kind of a single-loop extractor 701 with a wire loop 20 laterally connected to the catheter is shown in Fig. 7a. Loop 20 has no heat- or electrical-insulating coating and is specifically intended for extracting polyps and other formations under thermal action. At the stage of introduction into the hollow organ, the wire loop 20 is aligned longitudinally with

the catheter 701 (Fig.7b).

A further constructional modification of a single-loop extractor 801 intended for extracting polyps and similar formations by thermal action is shown in Fig. 8. Wire loop 20 has no heat- or electrical-insulating coating and has a distal part 21 oriented transversely to the catheter 802. Fig. 8b shows the shape of loop 20 during its introduction into a hollow organ.

By way of example of the performance of such equipment, the uses of extractors and the modes of electric power action for heating and additional heating provided by a pulsed power action for heating and additional heating provided by a pulsed power supply will now be discussed.

In accordance with medical indications, the location, dimensions and shape of the object to be extracted from the hollow organ, e.g. calculus in the ureter, are determined from preliminary diagnostic examination. Taking these factors into account, as well as the accessibility for catching, an appropriate extractor is selected. A wire or wires of appropriate length and diameter is/are selected and, after heating to about 150$^{o}$C, bent into the shape required for the operation. The extractor 1 may be heated by current from the pulsed power supply 103 through the coaxial cable forming the catheter 102.

The pulsed power supply operates in the following mode. The pulses at 50 Hz from the oscillator 107 are supplied to the processor 105. With the help of the control terminal 106, the operator sets an appropriate repetition rate and pulse duration. Processor 105 output controls shaper 109 which generates current

pulses of the required duration and pulse repetition rate. Thus the average current of the power supply can be regulated in steps from 0.2 to 5 A at an output voltage from 3-6V. The display 108 enables the operator to control the chosen mode of operation as desired. To heat the wire elements of the extractor in a preferred embodiment, a power supply current of 4A was used.

After the shape and cross-section have been corrected, the power supply is disconnected and the extractor is cooled to a temperature below 10°C, e.g., by irrigating with chlorethyl. During this process, it is deformed by helical torsion longitudinally of the catheter to the position shown in Figs. 3b and 4b in which the cross-sectional area of the deformed wire extractor is approximately equal to that of the catheter 2.

In this configuration the extractor and the catheter are introduced into the channel of an endoscopic device, e.g. a cystoscope when extracting calculi from the ureter, which is introduced into a hollow organ. The cystoscope is a familiar and conventional device for transporting the extractor to the ureter and, hence, has conventional auxiliary means in the form of an eyepiece lens, a moving means, an illuminating lamp, and a mirror, all of which are located in the region of a distal end of the tube. With the help of visual control provided by the cystoscope, the extractor is moved out from the tube and is led up to the gap between the calculus and the ureter wall. Then the catheter is further moved out to the position where the extractor is behind the calculus. Then the pulsed power supply is switched on at the chosen pulse repetition rate of about 20 Hz. Such a mode provides an average current of 1.6 A through the wire elements

14 of the extractor. The wires 14 of the extractor are heated for four seconds to 55$^{o}$C. Since the temperature interval for the extractor material shape reconstruction is 40-55$^{o}$C there occurs complete shape reconstruction of the extractor, i.e. it acquires the original pear-shaped basket form (Fig. 3a) and accomplishes the ureter dilatation. The average current through the wires of the extractor basket is then reduced by a factor of 8-10 by lowering the current pulse repetition rate and the pulse duration. By doing this it is possible to maintain an increased temperature of the metallic components of the extractor basket, compared to the surrounding body tissues. Hence, it is possible during shape reconstruction to keep the elastic modulus of wires made of titanium nickelide increased. In doing so, the possible trauma of the surrounding tissues due to the effect of electric current is avoided by the low output voltage of the power supply and the thermo- and electro-insulating coating 15 of the wires 14 forming the extractor basket.

The basket is then advanced to the calculus by a traction force, under the effect of which the wires 14 of the extractor are moved apart and the calculus reaches the extractor cavity. The pear-shaped basket of the extractor, with the orientation of its widened part towards the catheter, and the increased elastic modulus of the wires made of titanium nickelide provide high dilatation of the ureter in front of the calculus (in the direction of traction). This makes the subsequent traction of the calculus easier.

For the specific parameters of the extractor (its shape, thickness of wires and their number) the modes of heating and additional heating are easily optimised

and fixed in the form of the assigned operating modes of the pulsed power supply introduced in its processor. After this there is no need for operator control over the power supply.

Examples of use of the equipment will now be described.

Example 1. Extraction of calculus from ureter.

Patient M., 48 years old. The calculus is in the lower third part of the ureter. The extractor used is a six-wire basket 401 (Fig. 4a). The extractor is cooled to approximately $10^{o}C$. using chlorethyl and is shaped as a twisted rope (Fig. 4b).

The cystoscope is introduced through the ureter into the urinary bladder. The extractor is introduced into the cystoscope channel. The exit of the guide wire 22 of the extractor at the distal end of the cystoscope is determined visually. The extractor is introduced into the ureter by controlling the direction of the extractor movement by turning the cystoscope channel and its elevator. The extractor is moved in the ureter, with simultaneous rotation, and is brought in behind the calculus. Then the power supply 103 with the selected average output current 2.2 A for four seconds is connected to the cable-catheter. Thus the extractor is in a fully opened state (Fig 4a) and moves apart the ureter walls with the help of its wires forming the basket. The extractor is then smoothly withdrawn from the cystoscope and calculus traction starts. The calculus enters the extractor basket and freely rolls over it. During the subsequent traction, the smooth Teflon coating of the extractor prevents trauma of the ureter mucous coat. After the calculus leaves the ureter and enters the urinary bladder, the power supply is disconnected and the cystoscope is

removed from the urethra. The subsequent traction of the calculus through the urethra is carried out using the extractor without the cystoscope.

Example 2. Extraction of polyps

Patient T. A mushroom-shaped polyp is in the urinary bladder. The cystoscope is introduced into the urinary bladder. The urinary bladder is filled with physiological salt solution at temperature not below +30°C through a drainage opening of the cystoscope. The loop-shaped wire extractor 701 (Fig. 7a) is deformed lengthwise to the catheter in such a way that its thickness does not exceed the catheter thickness (Fig. 7b) and is introduced then through the cystoscope into the urinary bladder. At the control terminal 106 the mode with an average output current of 1.6 A is selected since the entire operation is carried out under visual monitoring. Under visual monitoring through the eyepiece of the cystoscope, the extractor is guided up to the polyp limb in such a way that it is half-way along the extractor. The power supply is then connected. The heated extractor with its loop catches the polyp limb (Fig. 7a). The power supply current is then increased to 5A and by catheter traction polyp electrocoagulation is carried out. In such an operation the polyp remains undistorted and can be used for subsequent analysis. For planar polyps, the operation is performed in the same way, but the extractor has the form of a scraper 801 (Fig. 8a). The angle of inclination of the operating part 21 of the scraper can be varied depending on the polyp location.

Example 3. Extraction of a member from bronchus

Patient K. There is a pea in the bronchus. The

extractor 501 is used (Fig. 5a). A bronchoscope is introduced through the mouth into the bronchus and under visual monitoring a distal end of the bronchoscope is guided up to the pea. The extractor 501 is cooled to $T = 10^oC$ and is deformed to the shape shown in Fig. 5b in such a way that the diameter of its cross-section does not exceed the catheter diameter. Then the extractor is introduced into the bronchoscope channel and advanced through it until it leaves the bronchoscope distal end. And then, under visual monitoring, the extractor is guided up to the pea and the larger loop of the extractor is advanced behind the pea. A control signal is supplied from the terminal 106 providing a current supply of 0.8 A to the extractor. This causes the shorter loop 18 to start its heating and reconstruction of its prescribed shape,i.e. the extractor is bent perpendicularly to the longitudinal axis of the catheter and then it becomes ring-shaped. As the small loop 18 of the extractor is reconstructed, it is advanced until it touches the pea. After the small loop reaches the pea, a signal from terminal 106 is supplied for increasing the current to 1.0 A and the heating and reconstruction of the large loop 17 commences. In so doing, it takes the form of an ellipse stretched along the catheter axis and is bent forming a half-ring which catches the pea at its distal part, the remote end of the half-ring engaging the distal part of the small loop 18. As a result of the extractor shape reconstruction the pea is held between the large loop 17 and the small loop 18 located perpendicularly to the catheter axis. By withdrawing gradually the bronchoscope together with the extractor, the pea traction is carried out.

Example 4. Extraction of calculus from ureter

Patient M. The calculus is in the ureter ostium and occupies two thirds of the entrance into it. The extractor 601 is used (Fig. 6a). The extractor is cooled to $T = 10^{o}C$ and deformed in such a way that its cross-section does not exceed the catheter cross-section (Fig. 6b). Through the cystoscope the extractor is introduced into the urinary bladder and under visual monitoring its distal end is led up to the ureter ostium. Then the extractor is moved in and, if necessary, turned round the catheter longitudinal axis, and then is brought in behind the calculus. A signal is supplied from the control terminal 106 and a current of 0.8 A is supplied to the extractor. During the heating the extractor is bent perpendicularly to the catheter axis and adopts a ring shape (Fig. 6a). The increase of the extractor elastic modulus during the heating allows the ureter to be widened by means of the extractor; the smooth Teflon coating of the extractor keeps the ureter mucous coat undistorted. Then by gradual withdrawal of the extractor the extraction of the calculus from the ureter is performed.

Numerous modifications may be made to the above-described embodiments. For example, instead of a single pair of supply conductors 10, 12, the wire elements can have individual conductors which permits independent control of the power supply to (and hence the temperature of) the individual wire elements. Thus in the embodiment of Fig. 5, each loop 17, 18 may have its shape controlled independently from a respective power supply. For especially complicated operations, three or more loops could be employed.

As described the wire elements 14 are heated by the passage of an electric current therethrough and this

has the advantage of compactness. However, if desired, electric heating elements of material not displaying the memory effect may be employed in close thermal communication with the elements 14. If it is desired to avoid the use of electricity, non-electrical methods of heating may be employed, for example hot air could be blown through the catheter 102. By suitable choice of the memory effect material the elements 14 could be passed along a thermally-insulating catheter 102, with cooling if necessary, and then heated by body temperature when they emerge from the end of the catheter.

Part of the length of each wire element 14 may be of non-memory effect material. Where there is a plurality of elements, some of them may be entirely of such material.

The present invention is not limited to medical devices, and the extractor device can be used to extract any type of article from a wide range of inaccessible locations such as inside a pipe or tube (for example the waste outlet of a domestic sink) or inside a chamber within a large piece of machinery which would be difficult to dismantle.

CLAIMS

1. An extractor device (101) comprising a catheter member (102) characterised in that at one end of the catheter member there is provided one or more wire elements (14) of a material having a thermomechanical shape memory characteristic, and means (10,12) extending along the catheter member enabling the elements (14) to be heated wherein the shape of the wire elements can be changed, in dependence upon temperature, between a first elongate configuration in which their overall cross-section is substantially the same as or less than that of the catheter member, and a second configuration for extraction.

2. A device as claimed in claim 1, wherein the means extending along the catheter member (102) are electrical conductors (10,12) connected between a controlled power supply (103) and the wire elements (14).

3. A device as claimed in claim 2 wherein the wire elements (14) are connected together at one end and, at the other end, at least one wire element (14) is connected to each electrical conductor.

4. A device as claimed in claim 3 wherein the wire elements (14) define a basket shape in their second configuration.

5. A device as claimed in claim 1 or 2, wherein the wire elements define at least first and second loops (17,18) of different sizes.

6. A device as claimed in claim 5, wherein the loops have different electrical resistance values.

7. A device as claimed in claim 1 wherein a wire element (19,20) defines a single loop which, in the second configuration, projects transversely of the catheter member (102).

8. A device according to any preceding claim, wherein the wire elements comprise an alloy having the following configuration:

| | |
|---|---|
| Titanium | 53.5-56.8% |
| $TiN_3$, $Ti_{11}Ni_{14}$, $Ti_2Ni$ | 2.0-10.0% |
| Nickel | Balance |

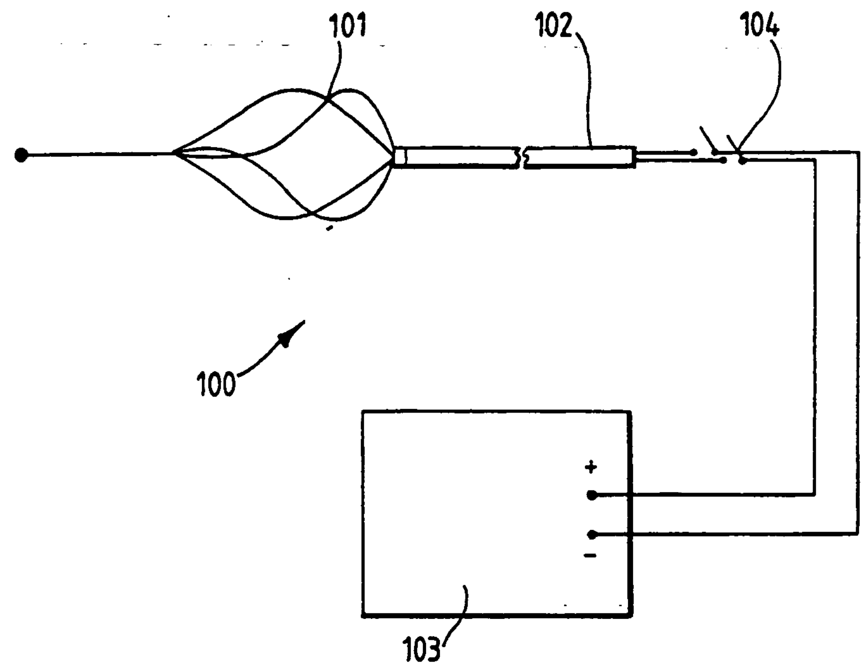
9. A method of extracting a member from a relatively inaccessible location employing an extractor device according to any preceding claim.

10. A method according to claim 9, wherein the temperature of the wire elements (14) is controlled between at least three temperatures, a first of which corresponds to the first configuration of the wire elements, and a second of which corresponds to the second configuration of the wire elements.

11. A material displaying a thermomechanical shape memory effect comprising a titanium nickelide composition.

12. A material according to claim 11 having the following composition:

| | |
|---|---|
| Titanium | 53.5-56.8% |
| $TiN_3$, $Ti_{11}Ni_{14}$, $Ti_2Ni$ | 2.0 - 10.0% |
| Nickel | Balance |


101
102
104
100
+
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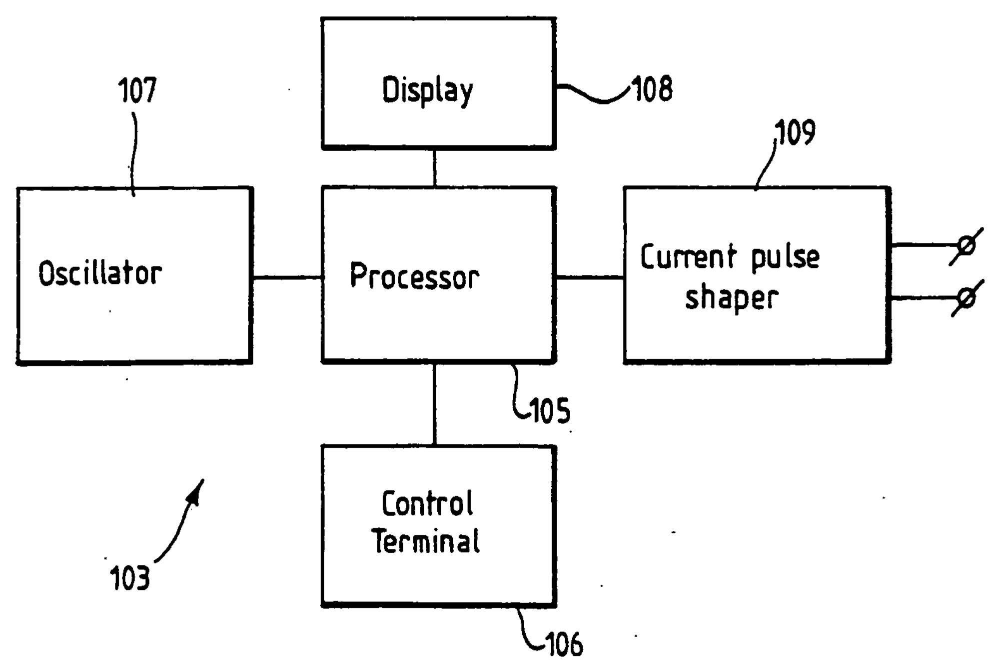
103

Fig. 1.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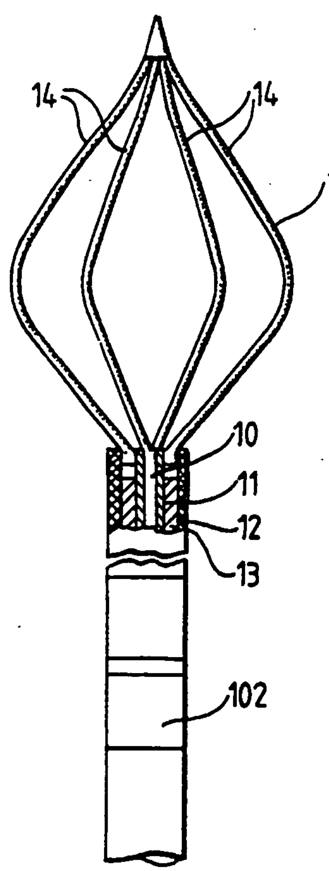


Fig.3a.

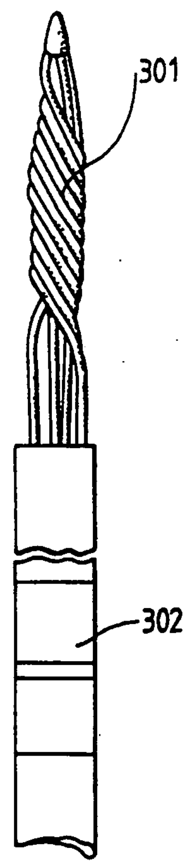


Fig.3b.

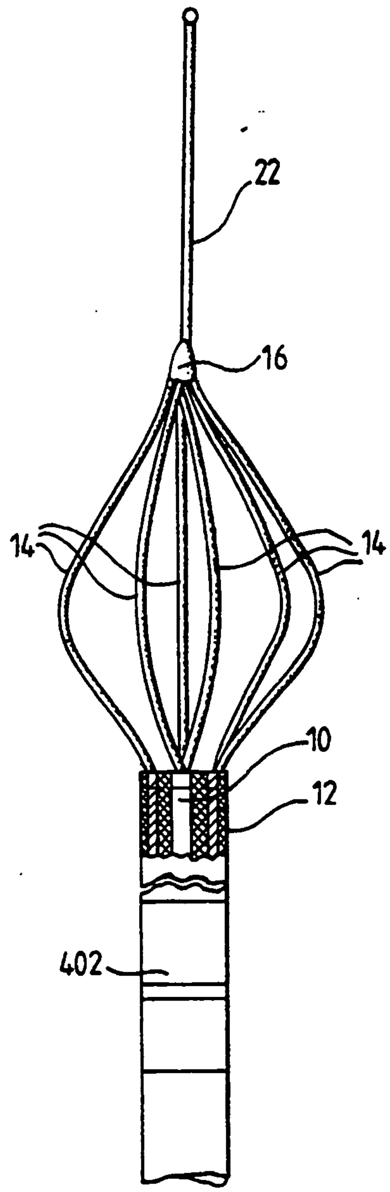


Fig.4a.

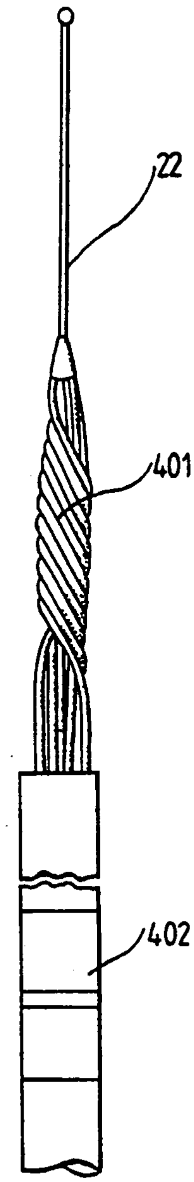


Fig.4b.

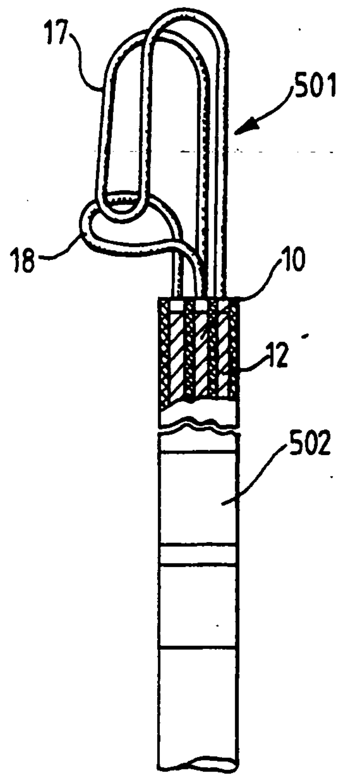


Fig.5a.

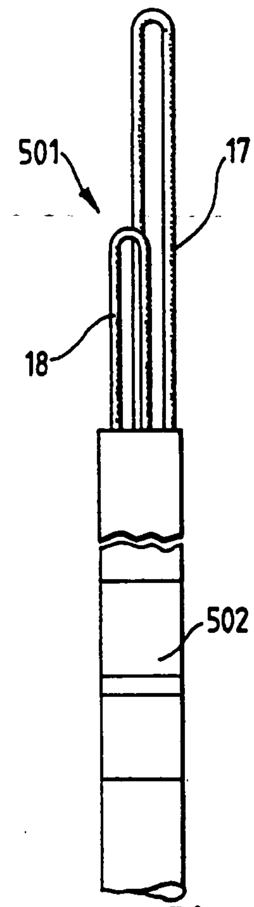


Fig.5b.

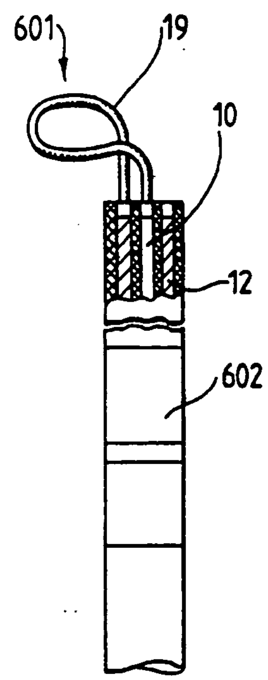


Fig.6a.

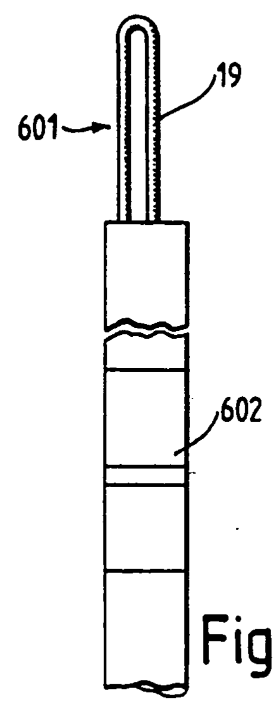


Fig.6b.

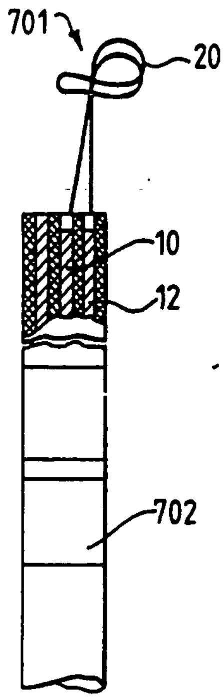


Fig.7a.

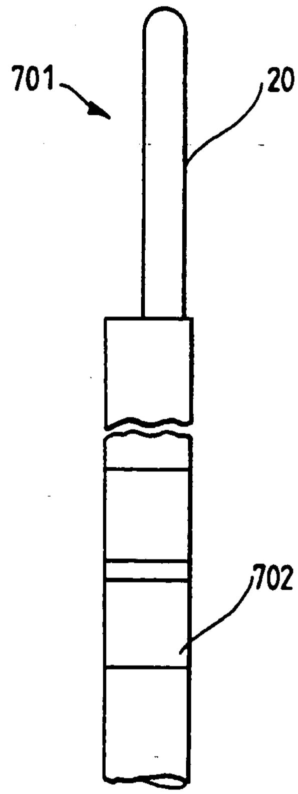


Fig.7b.

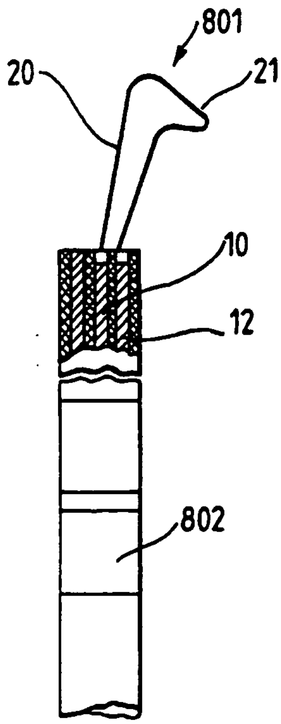


Fig.8a.

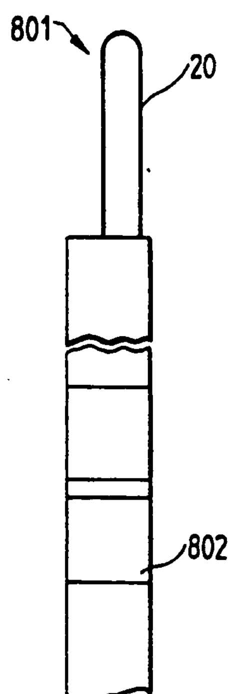


Fig.8b.

# INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 91/02216

**I. CLASSIFICATION OF SUBJECT MATTER** (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B17/22

**II. FIELDS SEARCHED**

Minimum Documentation Searched[7]

| Classification System | Classification Symbols |
|---|---|
| Int.Cl. 5 | A61B ; A61F ; C22F |

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

**III. DOCUMENTS CONSIDERED TO BE RELEVANT**[9]

| Category ° | Citation of Document, [11] with indication, where appropriate, of the relevant passages [12] | Relevant to Claim No.[13] |
|---|---|---|
| X<br>Y | EP,A,0 069 942 (OLYMPUS) 19 January 1983<br>see page 4, line 6 - line 16<br>see page 5, line 22 - line 26; figures 3-5<br>--- | 1-3,7-10<br>4-6 |
| X<br>Y | US,A,3 868 956 (ALFIDI ET AL) 4 March 1975<br>see column 3, line 27 - line 40<br>see column 5, line 18 - line 20<br>see column 5, line 42 - line 50<br>--- | 1-3,7-10<br>4-6 |
| X | WO,A,8 902 281 (TERUMO) 23 March 1989<br>see EP,A,418381 pub. date 27/3/91 col.4, lines36-57; fig.6<br>--- | 1-3,7-10 |
| P,,,<br>A | US,A,5 057 114 (WITTICH ET AL.) 15 October 1991<br>see column 3, line 45 - line 64<br>--- | 4 |

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° Special categories of cited documents : [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

**IV. CERTIFICATION**

| Date of the Actual Completion of the International Search | Date of Mailing of this International Search Report |
|---|---|
| 25 JUNE 1992 | 08.07.92 |
| **International Searching Authority** | **Signature of Authorized Officer** |
| EUROPEAN PATENT OFFICE | GLAS J. |

2

International Application No PCT/GB 91/02216

| III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET) | | |
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| A | see page 1, line 89 - line 95 | 8 |
| | --- | |

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 25/06/92
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
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| | | JP-C- | 1566602 | 25-06-90 |
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